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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	) MEDICAL DEVICE FOR) DISPENSING MEDICAMENTS
ULRICH SPECK et al	)
	) Group Art Unit 3763
Serial No. 10/528,666	)
	)
Filed March 21, 2005	)

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith for the convenience of the Examiner is an English translation of the International Preliminary Examination Report issued in International Application No. PCT/EP03/10480. This application is a national phase application based upon that international application.

Respectfully submitted,

WOOD, PHILLIPS, KATZ,
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By _____
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37 CFR 1.8
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 7, 2005.

Signature: Karen Sanderson

Name: Karen Sanderson

Translation

PCT/EP2003/010480

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SP-21212 WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/010480	International filing date (*day/month/year*) 19 September 2003 (19.09.2003)	Priority date (*day/month/year*) 20 September 2002 (20.09.2002)
International Patent Classification (IPC) or national classification and IPC A61L 29/16, 31/16		
Applicant BAVARIA MEDIZIN TECHNOLOGIE GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01 April 2004 (01.04.2004)	19 January 2005 (19.01.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP2003/010480

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-17

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages 1-31, filed with the demand

pages _____, filed with the letter of 15 September 2004 (15.09.2004)

☐ the drawings:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/010480

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 29, 30

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 29, 30.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

...5...

This report has been established without taking into account the amendments in the set of claims submitted with the letter of 15 September 2004. It is based on the claims and the description as originally filed. The reasons are as follows:

The amendments submitted with the letter of 15 September 2004 introduce substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed. The amendments are as follows:

- claim 1: "without a matrix or with a fixed matrix [...]" (the description refers to an inert matrix);
- "[...] with release of the active substance immediately upon contact with the tissue";
- claim 10: "[...] which does not lose its tendency to fold back [...]";
- claim 11: "of very smooth material [...], to which the drugs...";
- claim 12: "in the fully folded state [...] with an active substance solution with low viscosity".

The wording in the originally submitted claims used to characterise the claimed subject matter in terms of the desired result cannot be completely deleted from the claims, since it contains functional, yet

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

limiting, features which for clarification required additional technical features from the description. Since the original claim 12 uses the coating feature "immerse" and the description discloses (page 10, lines 9 and 10) coating methods such as immersing, smearing and spraying, this wording should be used in claim 12. The description does not support the omission of this technical feature, since, for example, other coating methods would then be conceivable, for example a plasma coating method, this method and other methods not being disclosed yet being covered by the new claim.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box III.1.

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

An objection has been raised against claims 29 and 30 relating to a method for treatment of the human or animal body by surgery (pursuant to PCT Rule 39.1(iv)).

Claims 29 and 30 of the present application, as worded, are directed to a method for treatment of the human or animal body by surgery.

Pursuant to PCT Rule 39.1(iv), this is not allowable.

(The newly submitted, reworded claims would be allowable as a "second medical use" in the production process.)

INTERNATIONAL [redacted]IMINARY EXAMINATION REPORT

International application No.
[redacted]/EP 03/10480

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-30	YES
	Claims		NO
Inventive step (IS)	Claims	13, 26, 29, 30	YES
	Claims	1-12, 14-25, 27, 28	NO
Industrial applicability (IA)	Claims	1-28	YES
	Claims		NO

2. Citations and explanations

The independent claims describe the subject matter for which protection is sought, as follows:

Claim 1:

A medical device for dispensing drugs, for the selective treatment of specific diseased sections of tissue or organ parts, characterised in that lipophilic, largely water-insoluble drugs that bind to various tissue components [...] adhere to the surface [...], at least one balloon catheter being provided as active substance carrier and the balloon catheter having a stenosis-cutting device that projects [...] or rests on the surface of the balloon.

Claim 22:

Method for producing the device according to claims 1 to 21, characterised in that the lipophilic drugs [...] are applied in a solvent-, suspension- or emulsion medium by immersing, smearing, spraying [...] onto the surface of the device [...].

The following citation is referred to for justification in this report:

US 5792158 A

The following document is also cited in this report:

US 5370614 A

I) Novelty

Novelty is acknowledged for the subject matter of all of claims 1 to 28 of the present application, since the prior art does not disclose any medical devices for dispensing drugs that have the following features (as per claim 1):

- balloon catheter with balloon;
- device located on the balloon for cutting stenoses, for example a wire mesh or a blade;
- lipophilic, largely water-insoluble drugs that adhere to the surface of the balloon which is used as the active substance carrier.

The prior art discloses devices for dilating vessels for stenosis treatment with, at the same time, dispensing of the active substance on the vessel wall, or devices for cutting stenoses using balloon catheters, the surfaces of the balloons, however, being simply impregnated with heparin.
Consequently, device claims 1 to 21 and method claims 22 to 28, relating to a method for producing the device according to claims 1 to 21, are considered novel (PCT Article 33(2)).

II) Inventive step

D1 discloses a balloon catheter for cutting and dilating stenoses (see column 2, lines 59 to 66).

The balloon catheter comprises a balloon, on which rest a number of curved blades. The blades are preferably made of metal, for example stainless steel (see column 3, lines 21 to 27). In this configuration, the balloon catheter is used to cut and dilate the stenoses (see column 3, lines 61 to 64).

The surface of the balloon is treated with heparin so as to reduce trauma to the vessel and to retard blood coagulation (see column 6, lines 24 to 28).

D2 discloses a balloon catheter with a sheath surrounding the balloon. The balloon carries a drug located in a viscous matrix. When the balloon is inflated following insertion into the vessel, the sheath twists (at a prepared point (line) of weakness) and the active substance is dispensed on to the vessel wall. The drug can be incorporated in the form of microcapsules, polymer-coated crystals or in a viscous matrix. The active substance is released and dispensed on to the vessel wall by the application of pressure, the balloon surface loaded with the drug coming into direct contact with the vessel wall and the active substance thus being dispensed on to the vessel wall.

Possible active substances include anticoagulants, antiplatelets, anti-thrombotics, growth factor blockers, receptor blockers and antagonists.

The active substance, which may be in a liquid, semi-liquid or crystalline form and may, when in the form of crystals, be coated or uncoated, adheres by means of microcapsules or the viscous matrix (see column 1, line 63 to column 2, lines 1 to 26 and 58 to 68; column 3, lines 38 to 49; column 4, lines 25 to 30 and 45 to 57).

The first method step in D2 for producing a balloon catheter consists in loading the outer sheath of the balloon with the matrix containing the active substance (see claim 1).

It can at this point be assumed by a person skilled in the art that he would have attempted to use the methods listed in claim 23 of the present application, for example using a solvent-, suspension- or emulsion medium and by immersing, smearing, spraying, for applying the "viscous matrix together with drug" to the balloon sheath.

It is obvious for a person skilled in the art to combine the teachings from documents D1 and D2, since D1 already includes dispensing of the active substance heparin to treat the vessels involved in treating the stenosis.

The present application aims to produce a balloon catheter with which it is possible to cut stenoses and at the same time effectively dispense an active substance on to the vessel wall of the vessel being treated.

The effective active substance release is achieved by applying the active substance to the balloon

catheter using the method as per claims 22 to 28. The invention therefore lies in the coating method and in the production of a device with which the active substance is applied, using the stated method, only to the covered area under the folds of the balloon (as per claims 13 and 26).

The feature of dependent device claim 13, that the active substance is located only under the folds of the balloon, was not previously disclosed by the prior art and is therefore considered novel and inventive.

The feature of dependent method claim 26, according to which the coating method coats only folded balloons, is considered novel.

The effect of the above features is that the drugs adhere to the balloons thus coated whilst they are being moved to the target location where the balloon is to be unfolded and are protected by the folding of the balloon even in arteries through which a large amount of blood flows.

Furthermore, the method can be implemented without the need for additional steps.